

### REMARKS

This Amendment is in response to the Office Action mailed August 27, 2007. As of the mailing of the current Action, claims 23-25, 27-29, 31-45, 47, 51, 68, and 69 are pending. Applicant presents herein, claim amendments and a response to the current Action.

Reconsideration is respectfully requested.

### REPLY TO ACTION

Claims 27 and 28 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly pointed out and distinctly claim the subject matter which applicant regards as the invention.

The office action on page 3 recites the limitations of "core" and "semipermeable coating" have insufficient antecedent basis for this limitation in independent claim 23.

Applicant amends herein, claims 27 and 28 to recite "said pellet" and "a semipermeable coating" such that the limitations of each of these claims have sufficient antecedent basis. Applicant respectfully request reconsideration and withdrawal of this rejection.

Claims 23-25, 27-29, 31-45, 47, 51, 68, and 69 have been rejected under 35 USC 103(a) as being unpatentable over Skinner (US Pat No. 6,210,710), in view of Miller (US Pat Application

Publication No 2005/0008690) further in view of Cristoferi et al. (US Pat. No. 5,252,339).

Applicant notes that rejections over prior art were made in the current Office Action. As such, in view of MPEP 707.07 that requires the Action to be complete as to all matters, Applicant response presented herein is based on the cited references. Applicant understands the MPEP requirement of completeness that the currently pending claims being allowable upon a showing that the claimed invention is patentable over these cited references.

The Office Action quotes the Skinner reference on page 4 reciting "the disclosed composition is beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets."

Applicant respectfully points to the declaration filed herewith under 37 CFR §1.132 by Dr. Manesh Dixit. Dr. Dixit addresses the Skinner reference beginning in item number 15. As stated by Dr. Dixit, "Skinner is an invention directed to compressed tablets. The subject application is related to a formulation comprising layered coatings on pellets." Dr. Dixit goes on to declare, in items 17-21, that "formulation considerations relating to compressed tablets and coated pellets are very different."

Dr. Dixit, beginning in the item number 22, addresses the Office Action characterization that suitable percentages through routine or manipulative experimentation to obtain the best possible results, are unattainable with in the art.

Additionally, Dr. Dixit addresses unexpected and unusual results based on the claims formulation percentage ranges. Dr. Dixit, refers to the pellet formulation that are loaded with active plus except it's in the range of 65-98.5% w/w as being "extremely difficult to formulate and percentage of active antics at the ends are crucial to produce consistent and stable layered pellets."

Applicant further directs attention to the NOTICE provided in Federal Register Vol. 72, No. 195, p. 57526, Wednesday, October 10, 2007, entitled "Examination guidelines for determining obviousness under 35 USC 103(a) in view of the Supreme Court decision in KSR International v. Teleflex Inc."

Applicant asserts the rejections set forth in the current office action do not follow the requirements for examination set forth in the Notice.

Specifically, applicant refers to page 57529 whereby a rejection may be sustained by "A. Combining Prior Art Elements According to Known Methods to Yield predictable Results." The Notice quotes the KSR decision and states "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant fields to combine the elements in the way the claimed new invention does. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art." Based on the declaration of Dr. Dixit, in item 34, Applicant asserts it would not have been obvious to a person of ordinary skill in the relevant field because as stated by Dr. Dixit a person of ordinary skill in

pharmaceutical formulations which do not look to formulations for compressed tablets to arrive at up formulation to be used in layered pellets.

Additionally, applicant refers to the referenced a Federal Register Notice, page 57532 discussing "Obvious to Try-Choosing From a Finite Number of Identified, Predictable Solutions, with a Reasonable Expectation of Success." Referring again to the declaration of Dr. Dixit, in item number 24, "there are thousands of active ingredients placed in dosage forms and there are thousands of known excipients to be combined with the active ingredients. Although certain aspects of active ingredients and excipients are known, their interactions based on combination and percentage composition are uncertain." These thousands of excipients represent a large number of excipients available to a formulations scientist can not fall under the "finite number of identified, predictable solutions" articulated in the KSR decision.

In view of this review of the Federal Register Notice that provides Examination guidelines for determining obviousness under 35 USC 103(a) in view of the Supreme Court decision in KSR International v. Teleflex Inc., applicant respectfully asserts that the rejections as set forth in the instant office action are contrary to these examination guidelines and therefore must be removed.

The declaration of Dr. Dixit further addresses the rejection based over with the Miller reference, in item 34, by stating that "a person having ordinary skill and knowledge in solid dosage formulations would not combine the multicompartment

disclosure with compressed tablet formulations to arrive at the invention as claimed in the subject application."

Applicant further addresses the rejection of claim 45 over Skinner in view of Cristofori et al. by asserting it not only does Dr. Dixit establish that a person having ordinary skill and knowledge of formulations science would not look to compressed tablet formulations as in Skinner and Cristofori, but including the disclosure of Cristofori does not cure the deficiencies of applying the skin or reference.

In view of the representations presented herein, and furthering a few of the declaration of Dr. Dixit, applicant asserts the currently ejection under 35 USC 103(a) cannot be properly sustained. Applicant respectfully request reconsideration withdrawal of this rejection.

Based on the amendments presented herein, applicant respectfully asserts the application is now in condition for examination on the merits. If the Examiner believes there are any issues that have not been resolved, the Examiner is invited to call the undersigned representative who is Attorney of record in this case.

Applicant: Romero  
Serial No.: 10/782,245  
Filed: February 18, 2004

The Commissioner is hereby authorized to charge our Deposit Account No. 19-0734 should any additional fee(s) be required in the filing of this paper to expedite the examination of this application.

Respectfully submitted,

Date: 11/27/07



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David W. Barman, Reg. No. 47,225  
Attorney for Applicant  
Robert M. Schwartz, P.A.  
2445 Hollywood Boulevard  
Hollywood, FL 33020  
Tel: (954) 924-0707  
Fax: (954) 924-0717